

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0036
CUSTOMER NUMBER: 181

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Schering Corporation
Schering-Plough Research Inst.
2015 Galloping Hill Road
Kenilworth, NJ 07033

Telephone: (b)(2)High, (b)(7)f

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	46	161	109	2	272
5. Cats	0	0	23	0	23
6. Guinea Pigs	0	4221	391	0	4612
7. Hamsters	0	0	20	0	20
8. Rabbits	0	322	80	4	406
9. Non-human Primates	83	621	126	23	770
10. Sheep	0	0	0	0	0
11. Pigs	0	6	0	0	6
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
GERBILS	0	1274	439	0	1713

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

IAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

(b)(6), (b)(7)c

DATE SIGNED

11/18/05

NOV 29 2005

November 15, 2005

Elizabeth Goldentyer, DVM
UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
Regulatory Enforcement and Animal Care
Eastern Region Office
920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Dear Dr. Goldentyer:

Listed below are comments to accompany the 2005 annual report for the facilities registered under certificate number 22-R-0036:

Site 1:

A. Environment Enrichment Program for Nonhuman Primates

All nonhuman primates are included in the environmental enrichment program. A total of 15 rhesus monkeys are exempted from pair-housing due to study requirements for monitoring food consumption. A total of 13 cynomolgus monkeys are individually housed due to the study design for telemetry readings. The study designs for both protocols were reviewed and approved by the IACUC.

A total of 63 nonhuman primates were individually housed due to aggressive behavior noted during the period of time when housed with suitable cage mates or no suitable partner has been yet identified.

B. Column "E" Explanation

1. A total of 8 cynomolgus monkeys developed unexpected adverse effects during a study evaluating an experimental compound. Seven of the animals were euthanized under the direction of the staff veterinarian at the time adverse effects were noted. One animal died before euthanasia could be performed. The primates were retrospectively added to Column "E".
2. A total of 2 dogs developed adverse reactions following oral dosing of an experimental compound. One dog died immediately after dose administration and the other was euthanized at the onset of the adverse reaction. The actions taken were under the direction of the staff veterinarian. The dogs were retrospectively added to Column "E".

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Site 2:

A. Environmental Enrichment Program for Nonhuman Primates

All nonhuman primates are included in the environmental enrichment program. A total of 18 nonhuman primates were individually housed due to aggressive behavior noted during the period of time when housed with suitable cage mates. A total of 12 primates were individually housed due to loss of cage mate or cage mate was temporarily separately housed to receive medical treatment.

B. Column "E" Explanation

1. A total of 5 nonhuman primates experienced transient convulsions while on study. The episode did not reoccur and the animals recovered, therefore no corrective treatment was necessary. The animals were evaluated by the veterinary staff during the course of the study. The primates were retrospectively added to Column "E".

A total of 10 nonhuman primates experienced adverse effects during [REDACTED] for new drug development. The studies were conducted under a protocol reviewed and approved by the IACUC and in accordance with FDA requirements. In addition, the study was conducted under veterinary supervision. All animals were monitored and were humanely euthanized when corrective measures were not successful. The primates were retrospectively added to Column "E".

2. A total of 4 rabbits experienced adverse effects during [REDACTED] for new drug development. Of the 4 rabbits, 2 died post-dosing, 1 was found dead without prior clinical signs and 1 was humanely euthanized. The studies were conducted under a protocol reviewed and approved by the IACUC and in accordance with FDA requirements. The study was conducted under veterinary supervision. The rabbits were retrospectively added to Column "E".